Radiant MEDICAL
250 Chesapeake Drive
Redwood City
California 94063
tel. +1(650)363.8000
fax +1(650)361.1400

K012512 1/2

Premarket (510[k]) Notification

JUN 11 2002

510[k] Summary of Safety and Effectiveness

Submitter Information

Company: Radiant Medical, Inc.

250 Chesapeake Drive
Redwood City, CA 94063
(650) 363-8000

Contact Person: Andrew Cleeland
Vice President of Regulatory, Clinical and Quality Affairs

Summary Date: August 3, 2001

Name and Classification

Proprietary Name: SetPoint® Endovascular Temperature Management System

Classification Name: Cardiopulmonary bypass heat exchanger (DTR) [21 CFR 870.4240]
Thermal regulating system (DWJ) [21 CFR 870.5900]
Percutaneous catheter (DQY) [21 CFR 870.1250]

Class: II

Predicate Devices

The SetPoint System has the same intended use as a number of commercially available medical devices, operates within an established range of temperatures, and uses existing, established technology

a) The Medtronic cardiopulmonary bypass circuit composed of the:
MYOTherm XP™ Cardioplegia Delivery System (K003724),
Bio-Cal 370 Temperature Control Module (K894980), and
Femoral cannula with introducer (K924642).

b) The Cincinnati Sub-Zero Hemotherm 400 (K811742).

c) The Augustine Medical, Inc. Bair Hugger® Patient Warming System (K873745).

d) The Medivance Artic Sun™ Temperature Management System (K010338).

e) The Arrow International Inc. Multi-Lumen Central Venous Catheter (K904404).

Chesapeake Drive
edwood City
alifornia 94063
el: +1 (650) 363.8000
ax: +1 (650) 363.2400

f) The Mallinckrodt Mon-a-Therm™ General Purpose Temperature Probe (K890484)

Intended Use

~~The intended use of the SetPoint® System is to raise, lower, and/or maintain blood temperature.~~ The SetPoint® System is indicated for use in cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care.

Description of Device

The SetPoint System is used to raise, lower, and/or maintain blood temperature. It consists of a single-use, heparin-coated, central venous catheter; a single-use, heat exchange cassette; an external controller; and associated accessories. The Controller unit has a user interface to select operating parameters and is connected to the Catheter via insulated lines. The catheter is designed for placement in the inferior vena cava via the femoral vein using a 10 Fr hemostatic introducer sheath. The Cassette is an integral part to the Catheter and an interface to the Controller.

Summary of Technological Characteristics

The SetPoint System uses established technology, materials, and construction techniques. The system employs standard heat conduction technology to warm or cool the blood using circulating warm or cool fluid in a closed loop system. The SetPoint System accomplishes this heat exchange through a catheter, located in the inferior vena cava, via the femoral vein, thereby adding heat to or removing heat from the blood by means of counter current heat exchange. The microprocessor based Controller circulates the fluid through the system and allows the fluid temperature to be raised or lowered as it passes over a thermoelectric unit within the Controller. Patient temperature is measured by the Controller using common 400 series thermistors.

Performance Test

The SetPoint® Endovascular Temperature Management System has been tested for system performance. In addition the Catheter has been tested for functionality in accordance to the BS EN ISO 10555, for biocompatibility in accordance to ISO 10993. The controller has been tested for electrical safety in accordance to EN 60601.

Conclusion

Based upon the successful performance tests and the comparison to the predicate devices, the SetPoint® Endovascular Temperature Management System consisting performs with similar safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Andrew Cleeland
Vice President of Regulatory, Clinical
and Quality Affairs
Radiant Medical, Inc.
250 Chesapeake Drive
Redwood City, CA 94063

JUN 1 1 2002

Re: K012512
Trade/Device Name: SetPoint® Endovascular Temperature Management System
Regulation Number: 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: NCX
Dated: May 31, 2002
Received: June 3, 2002

Dear Mr. Cleeland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

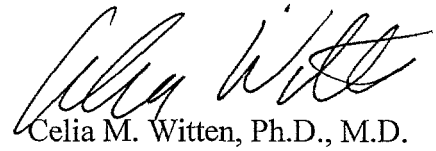
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012512

Statement of Indications for Use

The SetPoint® System is indicated for use in cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012512